

TCT-44

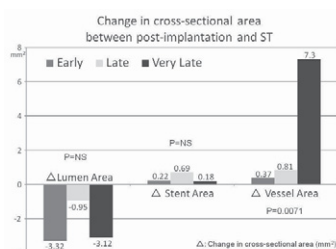
Differences in Coronary Intravascular Ultrasound Findings in Early, Late, and Very Late Stent Thrombosis After Drug-Eluting Stent Implantation

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Background: Stent thrombosis (ST) after drug-eluting stent (DES) implantation is a fatal complication. However, the incidence is quite low and the pathophysiology has not been fully evaluated. The aim of this study was to evaluate acute and long-term intravascular ultrasound (IVUS) findings in pts with ST.

Method: Between May 2004 and April 2010, 5005 lesions in 4682 pts were treated with DES. Of these, 36 pts (0.79%) with ARC definite ST were studied. Serial standard quantitative IVUS analysis was performed at the minimum lumen site before and after DES implantation and after ST.

Results: Early ST (n=20), late ST (n=8) and very late ST (n=7) occurred median 10 (IQR 2.5-14), 85 (IQR 35-260), and 675 (IQR 461-1020) days after DES implantation, respectively. There was no significant difference in baseline demographic features or baseline IVUS findings among the 3 groups. When post-DES implantation cross-sectional area (mm²) was compared among the 3 ST groups, pts with very late ST had a higher rate of change in vessel cross-sectional area compared with those with early and late ST (P=0.0071), although the rates of change in lumen and stent cross-sectional area among the 3 groups were similar. (Figure) Of 7 pts with very late ST, late incomplete stent apposition was observed in 4 pts, and 3 of these 4 pts discontinued dual antiplatelet therapy in the month prior to experiencing ST.



Conclusions: After DES implantation, late acquired incomplete stent apposition caused by positive remodeling is common in pts with very late ST. If late acquired incomplete stent apposition is observed at follow-up angiography, continuation of dual antiplatelet therapy may be warranted.

TCT-45

Predictors of Stent Thrombosis after Everolimus-Eluting and Paclitaxel-Eluting Stents: The Pooled SPIRIT II, III, and IV Randomized Trial Experience

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Background: Stent thrombosis (ST) is a devastating consequence of stent implantation. We sought to identify predictors of ST from a large cohort of patients treated with contemporary drug-eluting stents.

Methods: Data were pooled from the SPIRIT II, III, and IV randomized trials of the Xience V everolimus-eluting stent (EES) vs. the Taxus paclitaxel-eluting stent (PES). ST was adjudicated according to ARC definitions, and multivariable logistic regression was used to assess independent predictors of ST up to 1 year.

Results: A total of 4988 patients were included, with 31 definite/probable ST events (17 early, 14 late). In a model including pre-procedural characteristics alone, predictors of overall 1-year ST included: smoking, diabetes, presence of a side branch ≥ 2 mm; randomization to PES, LAD target vessel, prior MI and angina severity (Table). In a model including procedural characteristics in addition to baseline factors, the use of bailout stents and treatment of ≥ 2 lesions were the only additional factors associated with ST; a LAD target did not feature as a significant predictor. While early ST (0-30 days) was associated with baseline as well as procedural factors including smoking, LAD target, number of stents implanted; randomization to PES and maximal balloon pressure, the occurrence of late ST (31-365 days) was solely related to baseline factors including current smoking, presence of side branch ≥ 2 mm, and diabetes. Randomization to EES was a negative predictor of overall 1 year ST in both the baseline and full models.

Table: Predictors of 1-year ST

| Variable | Odds Ratio (95% CI) for ST | p-value |
|---|----------------------------|---------|
| Initial Model (baseline factors only) (n=4988) | | |
| Current Tobacco Use | 4.21 (1.91-9.31) | <.001 |
| Diabetes Requiring Treatment | 2.75 (1.26-6.00) | 0.011 |
| Presence of a side branch ≥ 2 mm | 2.68 (1.21-5.83) | 0.013 |
| Randomized Stent Type (EES vs. PES) | 0.39 (0.18-0.86) | 0.018 |
| LAD Target Vessel | 2.50 (1.06-5.86) | 0.035 |
| Prior MI | 2.29 (1.03-5.09) | 0.042 |
| CDS III or IV vs. CDS I or II Angina | 2.33 (1.00-5.41) | 0.049 |
| Full Model (baseline and procedural factors) (n=4988) | | |
| Current Tobacco Use | 3.79 (1.71-8.26) | <.001 |
| Number of Treated Lesions (2 or more vs. single) | 3.43 (1.58-7.44) | 0.002 |
| Presence of a side branch ≥ 2 mm | 3.14 (1.44-6.82) | 0.004 |
| Diabetes Requiring Treatment | 2.63 (1.20-5.73) | 0.016 |
| Randomized Stent Type (EES vs. PES) | 0.39 (0.18-0.86) | 0.017 |
| Bailout Stent Usage | 3.32 (1.22-9.05) | 0.019 |
| Prior MI | 2.53 (1.13-5.68) | 0.025 |
| CDS III or IV Angina vs. CDS I or II Angina | 2.35 (1.01-5.47) | 0.048 |

Conclusion: In a pooled analysis of ST predictors from the pivotal SPIRIT trials, baseline rather than procedural factors best predicted overall 1-year ST, and in particular, late ST. The randomized use of PES compared to EES was associated with higher 1-year ST, a finding that merits confirmation in other prospective analyses.

TCT-46

EuroSCORE Predicts Long-term Cardiovascular Events After Percutaneous Coronary Intervention in Patients with Left Main or Multivessel Coronary Artery Disease

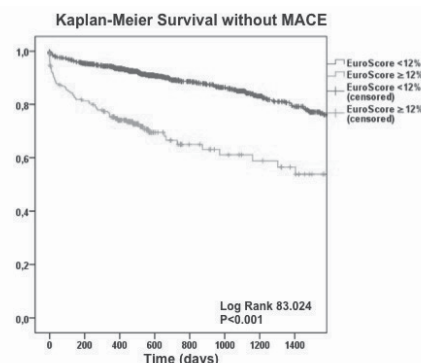
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Purpose: EuroSCORE was originally created for use in patients undergoing cardiac surgery. Because it is easy and objective, its application in other settings has been proposed. The aim of this study was to evaluate the EuroSCORE prediction of cardiovascular events in a large population of patients with left main or multivessel coronary artery disease undergoing Percutaneous Coronary Intervention (PCI).

Methods: From a single center prospective registry with 5611 consecutive PCIs performed from January 2003 to July 2008, 2314 were selected for analysis (first intervention in patients with left main or multivessel coronary artery disease). EuroSCORE was calculated and tested as a predictor of cardiovascular events at follow-up (MACE: combined occurrence of death, myocardial infarction and target vessel failure).

Results: Patients' age was 65 \pm 11 years and 78% were males. Mean follow-up was 23 \pm 16 months and there were 292 (12.6%) patients with at least one MACE, with 165 (7.1%) occurring in the first year. Median EuroSCORE was 2.86% (IQ: 1.49-5.84). After constructing a ROC curve, EuroSCORE evidenced an AUC of 68% (best cut-off 12%, used for comparisons): 9% of patients had high EuroSCORE and 23% of them had MACE, while in the remaining 91% only 6% reached the endpoint (p<0.001).

Multivariate Cox Regression analysis evidenced that EuroSCORE $\geq 12\%$ was a good predictor for MACE [HR 1.7 (1.2-2.5, p<0.01)]. Other independent predictors of MACE were: age, diabetes, peripheral artery disease, chronic renal failure and PCI in acute coronary syndromes. Drug eluting stents were protective.



Conclusions: Logistic EuroSCORE above 12% is an important long-term independent predictor of death, myocardial infarction or target vessel failure in patients with left main or multivessel disease undergoing percutaneous coronary intervention.

TCT-47

Evaluation of Everolimus-Eluting and Paclitaxel-Eluting Stents in Patients with Jailed Side Branches: The SPIRIT IV Trial

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Background: More frequent side branch compromise results in higher peri-procedural myocardial infarction (MI) rates with the TAXUS EXPRESS2 paclitaxel-eluting stent (PES) stent compared to the bare metal EXPRESS2 stent, possibly due to the thickness of the PES polymer. Although bifurcation lesions were excluded, the SPIRIT III randomized trial showed that patients having target lesions with small jailed side branches randomized to a thin strut and polymer XIENCE V everolimus-eluting stent (EES) compared to the thicker strut PES had lower 2-year rates of major adverse cardiac events due to fewer MIs and ischemia-driven target lesion revascularizations (ID-TLR). Whether these results are applicable to more complex bifurcation lesions has not been addressed.

Methods: In the SPIRIT IV trial, 3,687 patients were randomized 2:1 to EES vs. PES. Patients with up to 3 de novo native coronary artery lesions (maximum 2 lesions per epicardial vessel) of length ≥ 2.5 mm to < 4.25 mm were enrolled at 66 U.S. clinical sites, stratified by diabetes and lesion complexity. In contrast to SPIRIT III, side branches < 2 mm were allowed to be jailed. In this subset analysis, clinical outcomes in patients with or without jailed side branches (as assessed by the angiographic core laboratory, blinded to clinical outcomes) are compared according to stent randomization.

Results: Outcomes in patients with jailed side branches at 1 month and 1 year are shown in the Table.